

## DETAILED ACTION

### *Claim Objections*

The amendments to the claims filed on January 25<sup>th</sup>, 2008 are acknowledged and accepted by the examiner. The previous claim objections are hereby withdrawn.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 122-124 and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 122 recites the limitations, "wherein said shaft is characterized by an **absence of any bone engaging structures thereon;**" and "securing the shaft to the securing means such that the implant is retained within the drill hole and such that the **shaft is not engaged to the bone in a securing manner.**" The bolded text signifies limitations not adequately supported by the specification as originally filed. The ridges on the shaft can reasonably act as bone engaging structures and do indeed act as bone engaging structures indirectly through the securing means.

Claims 123, 124 and 126 recite the limitation, "said shaft ... characterized by an absence of any bone engaging structures." As described in claim 122, the shaft is deemed to contain bone engaging structures.

For examination purposes, the new matter limitations will not be given patentable weight with regard to claim analysis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42, 43, 67, 72-78, 87, 89 and 122-126 are rejected under 35 U.S.C. 102(e) as being anticipated by West, Jr. et al (US Patent 5,964,764).

West, Jr. et al disclose (**Figures 1-8**) a method comprising: drill a hole (**46**) through the bone of a patient; attaching a bone patellar tendon bone implant (**42**) to an anatomical structure other than the bone (the other bone in the joint); inserting through the drilled hole an attachment member comprising a hook (**35**) with a shaft (**20 and suture strands 36**); the shaft having locking means (the slanted portions leading to **32** as well as **32** itself; the locking means of the shaft (**20**) interact with a push nut (**24**) with receiving means (**26 and 28**); grasping the free end of the implant with the grasping hook; and securing the implant to the securing means increasing tension along the

Art Unit: 3733

implant before finalizing the secured position of the shaft and securing means. In **Figure 8**, one can see an enlarged portion of the drilled hole. In **Column 12, Lines 28-42**, it is stated that the entire device can be located within the drilled bore if desired.

The implant **(42)** can be reasonably interpreted as having an "enlarged bone plug" at the portion proximal to the hook **(35)** due to the bend "plugging the bone hole."

As can be seen in **Figure 4**, there is a gap between the shaft **(20)** and the bone hole thereby allowing some amount of motion between the shaft and bone hole, at least initially.

The excess portion of the shaft is trimmed when cutting the strands 36 (see **Column 9, Lines 54-67**).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61, 62, 79, 80, 83, 84 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over West Jr. et al.

West Jr. et al disclose all of the claimed limitations except for the device being made of metal from the group of titanium, stainless steel, cobalt-chromium-molybdenum alloy, titanium-aluminum vanadium alloy, and other alloys thereof as well as explicitly stating that a tension measuring device is utilized.

It would have been obvious to one having ordinary skill in the art at the time of invention to manufacture the device of West Jr. et al from an alloy claimed since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Further, since West Jr. et al already were concerned about tension being applied on the ligament and in regards to properly treating a knee, one would naturally measure the tension to ensure the knee is balanced and properly corrected for stability. It would have been obvious to one having ordinary skill in the art at the time of invention to provide a tension-measuring device in order to ensure the knee was properly corrected.

#### ***Response to Arguments***

Applicant's arguments filed January 25<sup>th</sup>, 2008 have been fully considered but they are not persuasive.

With regard to claim 42, as described in the current Office Action, the shaft is not "locked" to bone and is allowed some motion at least initially based upon the drawings.

With regard to claim 72, the shaft does go into central openings (surrounded by flanges) on the securing element as shown between a first opening (Figure 3) and a second opening (Figure 4). Therefore, the shaft moves "further" along and into the securing means until the implant is subjected to increased tension. It is noted that into does not require something to be encircled or enclosed, but rather bound in some manner which the central openings do.

With regard to claims 61, 62, 79, 80, 83 and 84, applicant asserts that West, Jr et al taught away from using metal. However, as clearly stated in Column 15, Lines 63-67 it says, "...it should be understood that using a bioabsorbable anchor device is not critical for obtaining a strong biological bond between the graft bodily tissue and the bone." Therefore other known materials would be appropriate as long as a biological bond could be formed which is well known with regard to certain coatings (hydroxyapatite, BMP, etc) on metal or porous surfaces for bone ingrowth.

With regard to claim 75, applicant asserts that West, Jr et al fail to disclose "locking means" being a series of slanted ridges formed along a long axis of the shaft. As previously described, the inner surfaces along the longitudinal axis of the shaft have a plurality of slanted ridges that engage the securing means. Element (34) between Figures 3 and 4 engage the plurality between the two images.

With regard to claims 76-78, applicant states confusion regarding the interpretation of member (24) as being a "push nut." After a quick text search for "push nut" in <http://www.google.com>, it is readily apparent in both many text hits as well as image hits that structure that is pressed into another structure to cap/fix a component is considered a push nut in the art. Further, considering the basic ideas of the words separately, that a nut is a relatively small structure that fixes a component and the adjective "push" to force in a direction would lead one to consider anything that fixes another object through the act of pushing together/away could be considered a push nut.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733